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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/212,367	12/15/1998	DAVID BAUNOCH	98.714	8537
20306	7590	09/21/2004		
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			EXAMINER	
			BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/212,367

### Applicant(s)

BAUNOCH ET AL.

### Examiner

William H. Beisner

### Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-4, 6 and 23-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 and 23-32 is/are allowed.
- 6) ☒ Claim(s) 2-4 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 2-4 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al.(EP 0 508 568) in view of Kinney et al.(US 4,001,460) and Louder et al.(US 4,399,433).

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With respect to claims 33, 3 and 4, the reference of Muller et al. discloses an apparatus which is capable of reprocessing a specimen from an infiltrating medium to an aqueous fluid which includes a processing chamber (112) with a sealable space for containing various liquids; a plurality of liquid containers (R1-R11) for holding a series of any known processing reagents; a fluid flow selector (129) for selecting a fluid to flow to the processing chamber wherein the plurality of liquid containing containers are connected to the fluid flow selector (129) by one or more first conduits (C1-C11) and wherein a second conduit (133) connects the fluid flow selector (129) to the processing chamber (112); temperature regulator (117) for regulating temperature in the processing chamber and including a heater and sensor in communication with the processing chamber (112) (See page 20, lines 15-25); and a computer control system (276,286) which includes a processor and memory (See page 32, lines 26-32, which discusses a microcomputer).

While the specific examples of the system do not include the sequential reprocessing as recited in instant claim 33, the disclosure of Muller et al. discusses a known process that can be performed by the disclosed system. Paraffin treated tissue sections are heated then contacted with xylene (clearant agent), then contacted with ethanol (dehydrant agent) and then contacted with aqueous hydrogen peroxide and saline (aqueous fluid) (See page 8).

In view of this disclosure, it would have been obvious to one of ordinary skill in the art to control the disclosed system of the primary reference so as to perform the known reprocessing by sequential control of reservoirs containing the required reagents to reprocess the samples as suggested by the reference of Muller et al. Regulation of temperature, pressure and flow would have been obvious to one of ordinary skill in the art while providing the required contacting

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conditions between the tissue sample and reagent while maintaining the contacting efficiency of the system.

The claims further differ by reciting the presence of separately valved infiltrating fluid.

The reference of Kinney et al. discloses an automated processing system which is similar to that of Muller et al. In addition to the reagents suggested by the reference of Muller et al., the reference of Kinney et al. discloses the use of separately provided paraffin reservoirs (13, 14) (infiltrating fluid) which are separately controlled for flow with respect to the other treating agents and discloses the use of purge clearant (9) and purge dehydrant (10).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the modified primary reference of Muller et al. such that tissue samples may also be automatically processed as suggested by Kinney et al. for the known and expected result of increasing versatility of the system of Muller et al. since the system of Muller et al. is disclosed as an improved means for accomplishing the sequential, multi-step, controlled processing of a slide surface mounted material.

Note the controller of Muller et al. is capable of controlling the fluid flow selector (129) to connect any of the containers to the processing chamber in any sequence.

While the reference of Muller et al. employs a pressure regulation system (110, 115, 120) to transport the processing liquids to and from processing chamber (112), the reference of Muller et al. does not specifically disclose a pressure sensor in communication with the processing chamber.

The reference of Kinney et al. discloses that it is known in the art to employ a pressure control system to transport the processing liquids to and from the processing chamber as done

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with the reference of Muller et al. The reference of Kinney et al. additionally discloses that it is known in the art to control the pressure within the processing chamber so as to improve the penetration of the tissue by the processing liquids (See column 7, lines 41-56).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the pressure control system of the reference of Muller et al. so as to vary the pressure within the processing chamber (112) so as to improve the penetration of the processing liquid as suggested by the reference of Kinney et al.

With respect to the claimed pressure sensor, the reference of Louder et al. discloses that it is conventional in the art to provide a pressure sensor (24) in communication with a processing chamber (10) so as to monitor the pressure within the chamber and control the pressure control and flow in response to detected pressures in the processing chamber.

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to provide the processing chamber (116) of the primary reference of Muller et al. with a pressure sensor for the known and expected result of providing an art recognized means for controlling and monitoring the pressure with respect to a tissue processing chamber. Monitoring the pressure within the chamber would be advantageous when providing the penetrating steps suggested by the reference of Kinney et al. Since the system of Muller et al. is already automated with respect to a microprocessor, automation of the conditions for enhancing penetration of the processing liquids would have clearly been within the purview of one having ordinary skill in the art.

With respect to claim 2, the reference of Muller et al. also discloses the use of a rotary valve (129).

***Allowable Subject Matter***

5. Claims 6 and 23-32 are allowed.

6. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claim 6, while the prior art of record discloses the use of purge dehydrant and/or purge clearant, the prior art of record fails to teach or fairly suggest a processor which controls the fluid flow selector so as to sequentially connect the processing chamber in a processing order which includes the container of clearing agent, the container of purge dehydrant, the container of dehydrant and then the container of aqueous solution to reprocess a specimen held in the chamber.

With respect to claims 23-32, while the prior art of record discloses the use of purge (contaminated) dehydrant and/or purge (contaminated) clearant, the prior art of record fails to teach or fairly suggest a processor which controls the fluid flow selector so as to sequentially connect the processing chamber in a processing order which includes the container of clearing agent, the container of contaminated dehydrant, the container of dehydrant and then the container of aqueous solution to reprocess a specimen held in the chamber.

***Response to Arguments***

7. Applicant's arguments with respect to claims 2-4 and 33 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue with respect to the references of Mueller et al. and Kinney et al. neither of the references teaches or suggests that the pressure is regulated with a processor. Applicants point to page 20, lines 29-37, of Mueller et al. arguing that Mueller et al. merely discloses manual regulation and point to column 5, lines 11-68, arguing that Kinney et al. merely discloses on/off control.

In response, the reference of Mueller et al. clearly discloses automated control. See specifically page 21, lines 18-24, which states that processing fluid flow control system include computer actuation which is clearly associated with automated control. Furthermore, while the reference of Kinney et al. may not specifically disclose the use of a microprocessor, the combination of the references clearly suggests to one of ordinary skill in the art the obviousness of the use of a microprocessor for regulation of the flow of processing to, within and from the processing chamber.

### ***Conclusion***


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
William H. Beisner  
Primary Examiner  
Art Unit 1744

WHB